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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,964	03/25/2004	Xiang-Jin Meng	AM100878-P1	7042

7590 09/07/2005

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,964	MENG ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *11-14, 15(d-f), 17 and 23-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 15(a-c), 16, 18-22 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/25/4 and 11/4/4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, (claims 1-10, 15 (a)-(c) and 16-22) in the reply filed on July 29, 2005 is acknowledged.

The traversal is on the ground(s) that unity of invention is seen throughout the chimeric PCV1-2 molecule, which links it with all of the other products and methods claimed. However, since this US case was not filed under 35 USC 371, unity of invention is not a factor of consideration for a restriction requirement.

Applicant believes that the unifying factor of the chimeric PCV1-2 molecule will require overlapping searches for Groups II and VII.

A review of Groups II and VII have been considered in view of the subject matter of Group I. Group II is drawn to a method of making a polypeptide and Group II is drawn to an infectious chimeric PCV2-1. With respect to either Group II or VII, the method and the product are separately classified from the product of Group I. In addition, the product of group I can be made by an alternative method. The alternative method is all that is required to properly show patentable distinctness according to MPEP § 806.05(h).

While the product of Group VII is structurally distinct from the product of Group I, a review of the working examples presented instantly indicates that the gross pathology and immunogenicity of pigs inoculated with either construct are very similar. Therefore, applicant is persuasive with respect to Group VII, which is now rejoined with Group I.

With respect to different classification for each of the groups and search burden, applicant points out that the Office routinely issues patents that are classified in various statutory classes.

Applicant is correct. However, it should be noted that the classifications on issued patents cover areas of search required to find, retrieve and apply relevant art for the single elected invention claimed.

Applicant also points out that the Office often grants patents to claims drawn to a product as well as the process of making and using that product.

Applicant is correct in this as well. In the instant application, applicant has elected the product of Group I (and VII). Applicant is not barred from rejoinder of all the elected product and process claims using that product, if the product is found allowable and all of the process claims maintain dependency on the allowed product.

The following is a recitation of M.P.E.P. §821.04, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined . If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.
>
> In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the

> rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Applicant additionally argues that the restriction requirement forces applicant to forfeit patent coverage of all aspects of their invention. However, it is not clear how the restriction equates to forfeiture as each Group is patentably distinct. That is, the restriction determines that each Group can support a separate patent and cannot be subject to a double patenting rejection pursuant to surrender of a terminal disclaimer.

Applicant also discusses the great time and expense to file, prosecute and maintain seven different patents. However, this argument is irrelevant for consideration of a restriction between

patentably distinct groups. Additionally, the quantity of patents issued to an applicant is usually an indicator of success in commerce.

Applicant requests modification of the restriction requirement. Specifically, applicant requests that Groups V and VII be rejoined with Group I. Applicant's arguments have been fully considered, but are found unpersuasive with respect to Group V for reasons explained above. However, should the elected product of Group I (now encompassing the subject matter of Group VII) be found allowable, the method of Group V can be rejoined, assuming that co-dependency is maintained throughout prosecution.

The requirement is still deemed proper and is therefore made FINAL.

It is noted that the restriction requirement erroneously included claim 17 with Group I. This claim should have only appeared in Group III since it is further describing a polypeptide.

Claims 11-14, 15(d-f), 17 and 23-31 are withdrawn from consideration due to nonelected inventions. Claims 1-10, 15(a), 15(b), 15(c), 16, 18-22 and 32 are under consideration.

Double Patenting

Claims 1-4, 6-10, 15(a-c), 18-22 and 32 of this application conflict with claims 1-9, 13(a-c), 14-18 and 25 of Application No. 10/314,512. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and

useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4, 6-10, 15(a-c), 18-22 and 32 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9, 13(a-c), 14-18 and 25 of copending Application No. 10/314,512. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 5 requires that the nucleic acid molecule contains a mutation at position 328 from (C to G) and/or a mutation at position 573 from (A to C). A sequence alignment of SEQ ID NO: 2 against Genseq database accession no. AAL57177, submitted October 27, 2003 by applicant in WO 2003049703-A2 reveals an exact match, see the sequence alignment provided. According

to the alignment, position 328 is T, so it is not clear how C or G are derived as claimed. Further; position 573 matches as A, which indicates that there is no change from an original sequence at position 573 from A to C. Therefore, it is determined that there is no adequate disclosure present for the mutations claimed.

Claims 7 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the plasmid designated as ATCC Patent Deposit Designation PTA-3912 is required to practice the claimed invention because it is a recited element in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of PTA-3912. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the recited plasmid and it is not apparent if it is readily available to the public. Applicant's deposit statement in the specification on pages 18 and 36 do not indicate the extent of public availability. On page 36, the specification states that certain DNA clones were deposited under the conditions mandated by 37 CFR 1.808. However, it cannot be determined if the DNA clones discussed are the same as the claimed deposited plasmid. The MPEP § 2404.01 states that: "A mere reference to a deposit of biological material itself does not necessarily mean that the biological material is readily available." If the deposit is made under the terms of the Budapest Treaty, then an

affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Claims 15(a-c), 16 and 18-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protecting a pig against PMWS with a chimeric PCV1-2, does not reasonably provide enablement for treating PCV2 associated disease with PCV1-2 or preventing or treating PCV2 infection with a PCV2-1 chimera or any chimeric circovirus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a vaccine that protects pigs against PMWS which comprises a carrier and an avirulent, infectious chimeric porcine circovirus. The claims also encompass a method of protecting a pig against PMWS by administering a live chimeric porcine circovirus. While the working examples administer the constructs to pigs and clearly demonstrate seroconversion along with a lack of viremia and histopathological lesions (see Example 15 through Table 10), there are no challenge experiments with either PCV1-2 or PCV2-1. However, Fenaux et al. (Journal of Virology. 2004; 78 (12): 6297-6303) clearly demonstrate protection with PCV1-2. The state of the PMWS/PCV art is unpredictable, see the teachings of Krakowka et al. (Viral Immunology. 2002; 15 (4): 567-582). Krakowka et al. teach that clinical

induction of PCV-2 results in two distinct disease syndromes, PMWS and porcine dermatitis and nephropathy syndrome (PDNS). Krakowka et al. also teach that although PMWS symptoms have been artificially stimulated in piglets by co-inoculation of PCV-2 and another immune stimulant, such as PPV, PRRS or an oil-based emulsified immunogen, PDNS has not been reproduced, see the abstract and the first full paragraph on page 578. While manifestation of PMWS lesions were reduced upon administration of cyclosporine (Cys), the amount of PCV-2 virus produced is augmented. Krakowka et al. discuss the clinical ramifications of high titers PCV-2 viral titers and the host's immune system, see the results and discussion sections. There is no teaching in the prior art or the disclosure that suggests that administration of any of the instant porcine circovirus chimera (more specifically PCV2-1) would induce specific T cell immunity as well as neutralizing antibodies against PMWS and PCV that would be well tolerated by a host.

The level of predictability to one of ordinary skill in the art for vaccine development is low. One of skill in the art would have doubt the instant vaccine's effectiveness and may even conclude that the claimed composition may cause detrimental effects if administered as a vaccine due to the lack of guidance provided in the disclosure. There is no evidence in the working examples for treating or preventing PMWS or PCV infection with any porcine chimera except PCV1-2. For these reasons, it is determined that the claims are not enabled for treating and protecting pigs against viral infection or developing PMWS with any PCV chimera or PCV2-1 commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allan et al. (US 6,217,883 B1) in view of Caggana et al. (Journal of Virology. 1993. 67 (8): 4797-4803), Lustig et al. (Journal of Virology. 1988. 62 (7): 2329-2336) and Mahe et al. (Journal of General Virology. 2000; 81: 1815-1824) (All of these references are cited on the 1449).

Claims 1-3 are drawn to an infectious, chimeric nucleic acid molecule of PCV1-2, where ORF2 of PCV-2 replaces ORF2 of PCV-1. Claim 32 is drawn to the reciprocal of this construct.

Allan et al. (US 6,217,883 B1) teach a vector comprising PCV2 ORF2 in a recombinant virus, see claims 14 and 15. Allan et al. do not teach the recombinant carrier virus as PCV1 or replacing ORF2 with the recombinant PCV2 ORF2 (or vice versa) to generate a chimeric PCV.

Caggana et al. teach replacing the 5'end of an avirulent coxsackie virus with the corresponding 5' end of a pathogenic virus, generating an analogous construct to the instant PCV1-2. Lustig et al. teach replacing an avirulent capsid protein of a sindbis virus within a virulent sindbis virus background, generating an analogous construct to the instant PCV2-1.

One of ordinary skill in the art at the time the invention was made would have been motivated to replace the ORF2 of PCV1 with the corresponding ORF2 of PCV2 (or the reciprocal thereof), taught by Caggana et al. and Lustig et al. to generate a less virulent, hybrid PC virus that has most of the immunorelevant viral epitopes, see the abstract of Mahe et al.

Mahe et al. teach that the epitopes between PCV1 and PCV2 are cross-reactive, see the first full paragraph of the first column on page 1822, and that ORF2 is the PCV capsid protein, see the introduction section. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for making either PCV hybrid construct because Allan et al. claim expressing ORF2 in virulent and avirulent viral vectors, see claims 16 and 17, and replacing corresponding pieces between avirulent and virulent virus strains to generate chimeric viruses that have reduced pathogenicity is taught by Caggana et al. and Lustig et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Allowable Subject Matter

The prior art does not teach or suggest SEQ ID NO: 2 or a nucleotide sequence that is at least 95% homologous to SEQ ID NO: 2.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Primary Examiner
Art Unit 1648